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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.               | CONFIRMATION NO.            |
|--|-------------|----------------------|-----------------------------------|-----------------------------|
| 10/787,526   | 02/26/2004  | C. Allen Chang       | 3102/2020                         | 6448                        |
| 35743  | 7590        | 09/20/2007           |                                   |                             |
| KRAMER LEVIN NAFTALIS & FRANKEL LLP<br>INTELLECTUAL PROPERTY DEPARTMENT<br>1177 AVENUE OF THE AMERICAS<br>NEW YORK, NY 10036 |             |                      | EXAMINER<br>JONES, DAMERON LEVEST |                             |
|  |             |                      | ART UNIT<br>1618                  | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>09/20/2007   | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

**Office Action Summary**

Application No.

10/787,526

Applicant(s)

CHANG ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 15 and 20 is/are rejected.
- 7) ☒ Claim(s) 16-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 8/20/07 wherein claims 1-8, 10-14, and 21-46. In addition, the Examiner acknowledges receipt of a request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/20/07 has been entered.

**Note:** Claims 9 and 15-20 are pending.

## **RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENTS**

2. The Applicant's arguments and/or amendment filed 8/20/07 to the rejection of claims 1, 3, 4, 7-9, and 17 made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive because the claims were amended to overcome the rejection and/or canceled. Therefore, the said rejection is hereby withdrawn.

## **112 REJECTION**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

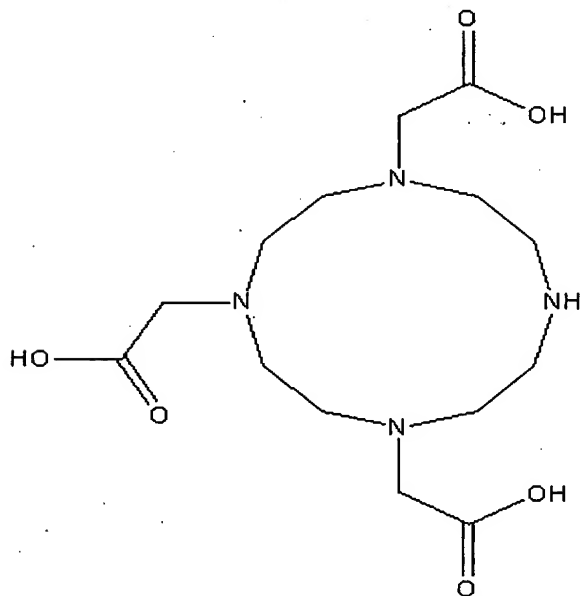
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9, 15, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 9, line 14: The claim as written is ambiguous because of the term 'comprising'. In particular, it is unclear if Applicant intended to write the term 'of' instead of 'comprising' since the formula in line 15 is that of the organic ligand. However, the use of the term 'comprising' is open terminology and allows for other components to be present other than the (i.e., the specific ligand set forth by Applicant) ligand. Thus, it appears as if the wrong term was term.

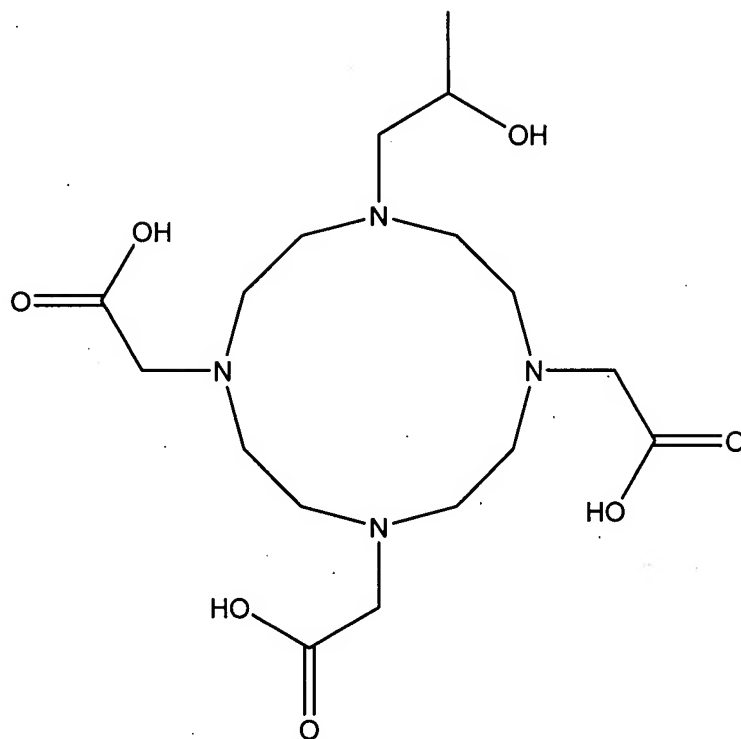
Claims 15 and 20: The claims as written are ambiguous because the definitions of L and L' set forth in the claims are not consistent with the values of the organic ligands (L and L' of independent claim 9). The structures of L and L' as set forth in claims 15 and 20 are:



1,4,7,10-tetraazacyclododecane-1,4,7-triacetic acid

and

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1,4,7-tris(carboxymethyl)-10-(2'-hydroxypropyl)-1,4,7,10-tetraazacyclododecane

which differ from the organic ligand structures of independent claim 9 in that R2 is methyl and/or R1 is not hydroxypropyl. Thus, Applicant is respectfully requested to make the appropriate corrections in order that one may ascertain the full scope of the instant invention.

### CLAIM OBJECTIONS

5. Claims 16-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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## COMMENTS/NOTES

6. The Examiner did not call Applicant in regards to the 112 rejections above because the changes necessary to address the rejections are not minor.

7. For clarity of the claims, the following changes are suggested; (1) in claim 9, line 1, delete 'contrast agent' because it confuses the claim. Why? Well, in claim 9, line 12, the phrase 'contrast agent' appears which is not the same 'contrast agent' in line 1. Also, in claim 17, the contrast agent that Applicant is referring to is the second occurrence of 'contrast agent', but with contrast agent present in line 1 of claim 9, the claims become somewhat confusing. (2) In claim 17, line 2, after the term 'salt' insert 'excipient' for clarity of the claim. (16) Claim 16 should be deleted because it does not further limit claim 9. Specifically, review of claim 9 indicates that both L and L' are the same organic ligand. Thus, claim 16 which states that the ligands are the same does not further limit claim 9.

8. It should be noted that no prior art has been cited against the claims. The claims (claims 9 and 16-19) are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the compositions having the limitations as set forth in independent claim 9.

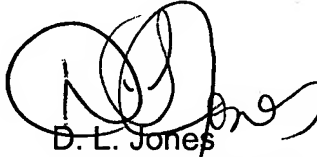
**Note:** Claims 15 and 20 while dependent on claim 9, do not read on the invention as set forth in amended claim 9.

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9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones  
Primary Examiner  
Art Unit 1618

September 12, 2007